MAY 02 2002

K021117

510(k) Summary

1.	Submitter name and address:	Thermosurgery Technologies Inc. (formerly RDM International, Inc.) 2901 West Indian School Road Phoenix, AZ 85017-4162
	Establishment registration:	2027460
	Phone:	602-264-7300
	Contact person:	Gene R. Hedin, CEO
	Date summary was prepared:	March 15, 2002
2.	Trade name:	TTI ThermoMed™ Model 1.8 Instrument
	Common name:	Localized current field radio frequency instrument
	Classification name:	Device, Electrosurgical, Cutting and Coagulation Accessories, Class II
	Product code / Regulation no.:	GEI / 878.4400
3.	Predicate device:	K894166 – RDM Thermosurgery™ Localized Current Field RF Instrument
	Product code / Regulation no.:	GEI / 878.4400/ClassII
4.	Description of device:	The TTI ThermoMed device delivers controlled localized current field (LCF) radio frequency (RF) heat to selectively destroy certain diseased tissue. RF energy is delivered to the dermal surface via a hand held wand with an autoclaveable energy applicator. For convenience, an audial and visual signal indicates the elapsed treatment time in 30-second intervals after the selected target temperature is reached.
5.	Intended Use:	The device is intended to treat benign superficial dermatological indications that includes; warts, molluscum contagiosm, angioma, fibroma, seborrheic keratoses, acrochordon, syringoma, hydrocystoma, clavus, actinic keratoses, keloids, epidermoid cysts, cystic acne, cutaneous leishmaniasis, atypical mycobacteria, and dermatophytosis. Treatment of patients with implanted electronic devices, patients with metallic implants and pregnant women is contraindicated.
6.	Technological comparison:	This Special 510(k) device modification is submitted to provide notification of a change in the temperature controller from analog to digital control. No negative effects on safety or effectiveness have been found after the risk analysis and risk mitigation process. This change is rated as a "minor level of concern" per the May 1998 software guidance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 02 2002

Mr. Gene R. Hedin
President and CEO
Thermosurgery Technologies, Inc.
2901 West Indian School Road
Phoenix, AZ 85017-4162

Re: K021117
Trade/Device Name: TTI ThermoMed™ Model 1.8 Instrument
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 5, 2002
Received: April 8, 2002

Dear Mr. Hedin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

(As required by ODE for all 510(k) received after Jan. 1, 1996.)

510(k) Number: K021117

Device Name: TTI ThermoMed™ Model 1.8 Instrument

Indications For Use:

The TTI ThermoMed™ Model 1.8 Instrument provides the therapeutic modality to treat the following benign diseases and conditions:

1. Warts
2. Molluscum Contagiosum
3. Angioma
4. Fibroma
5. Seborrheic Keratoses
6. Acrochordon
7. Syringoma
8. Hydrocystoma
9. Clavus
10. Actinic Keratoses
11. Keloids
12. Epidermoid Cysts
13. Cystic Acne
14. Cutaneous Leishmaniasis
15. Atypical Mycobacteria
16. Dermatophytosis

(Do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021117

Prescription Use ✓ or Over-The-Counter Use ____
(Per 21 CFR 801.109)